c.) Remarks:

1.) Claim rejections – 35 U.S.C. § 112, second paragraph.

Paper No. 12 rejected claims 21-40 as being indefinite under 35 U.S.C. § 112. Specifically, for Claim 21, the term "including" was found to be vague and indefinite. Claim 21 has been amended to cure this concern. The term "including" has been replaced with the phrase "having an amino acid sequence Lys-Pro-Val at the C-terminal" to more clearly recite that the polypeptide and the amino acid sequence are not separate.

Paper No. 12 states that Claim 36 recites the terms "biologically functional equivalent of anything of the foregoing." Applicant respectfully points out here that the terms identified in Paper No. 12, "biologically functional equivalent of anything of the foregoing" do not appear in Claim 36. However, these terms are found in Claim 21. Assuming that Paper No. 12 meant to identify Claim 21, Applicant has amended Claim 21 to eliminate the identified terms and amend the claim with "α-MSH peptide comprising α-MSH or an α-MSH derivative having an amino acid sequence Lys-Pro-Val at the C-terminal. Applicant requests the 37 U.S.C. § 112 second paragraph rejections be withdrawn consistent with the above amendments.

2.) Claim rejections under – 35 U.S.C. § 103

Claims 21-40 were rejected in Paper No. 12 as being *prima facia* obvious and thus unpatentable over a single reference, Rathjen et al. (WO 93/012211) (hereafter "Rathjen"). Applicant respectfully traverses the rejection.

The basic requirements for a finding of *prima facie* obviousness involve three basic criteria. "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference...must teach all the claim limitations." MPEP § 2143.

First, motivation to modify the reference, Rathjen, as asserted in Paper No. 12, is not supported in this single reference cited against the instant application. Rathjen focuses on numerous peptides derived from Tumor Necrosis Factor (TNF), whereas the instant application focuses on α-MSH and α-MSH derivative peptides. No suggestion exists in Rathjen that the KPV moiety is the functional portion in the vast array of peptides listed in Rathjen. Further, no mention is made as to the importance of KPV occupying the C-terminal of the peptide. While it is true that Rathjen contains an extensive list of peptides derived from TNF, including one peptide that contains the C-terminal sequence KPV, no reference is made in Rathjen that suggests KPV is the active portion of any of the peptides listed. To the contrary, Rathjen concludes only that a wide range of peptides abrogate TNF and/or LPS toxicity. (Rathjen, p. 4, lines 31-33). The data presented in Rathjen that contain a KPV moiety at the C-terminal of a peptide suggested that there was less activity in such a peptide as compared to other peptides upon which Rathjen places importance, i.e., peptides identified as peptide 1, peptides 302 and above. (Rathjen, p. 28 Table 4; Figure 12). Rathjen does not discuss any peptide containing KPV at the C-terminal when discussing activity or studies of individual peptides. (Rathjen, pp. 23-32). Notably, a peptide containing KPV at the C-terminal is absent from other tables in the Rathjen disclosure. Nothing in the Rathjen disclosure suggests modification of TNF to a KPV tripeptide or a KPV tripeptide at the C-terminal of a peptide. The disclosure devotes itself to other proteins in such a way that it effectively teaches away from a KPV protein.

However, the instant claims, as amended, are directed to the specific KPV moiety at the C-terminal of the polypeptides recited in the claims. The instant application includes KPV as a component of each peptide to be used in the kit claimed. In contrast, KPV, in its only representation in Rathjen, exists as does KPV, or any tripeptide for that matter, in any number of other proteins. For example, KPV exists in the amino acid sequences of both TNF and adrenocorticotropic hormone. It is improper to conclude that one ordinarily skilled in the art would be motivated to modify Rathjen, which never focuses on the KPV moiety, to effect the kit claimed in the instant application.

Second, Rathjen does not support a reasonable expectation of success in creating the invention claimed in the instant application. No term in Rathjen suggests a sunburn treatment kit. Based on the disclosure of Rathjen, the peptide containing KPV at the C-terminal had less efficacy than many of the other peptides disclosed. (Rathjen, Table 4, p. 28).

Third, limitations in the pending claims are not found in Rathjen. No mention of a kit is made in Rathjen. Rathjen does not include a teaching of an impermeable packaging. Rathjen does not include teaching for a carrier for application to cutaneous inflammation caused by exposure to ultraviolet radiation, and Rathjen makes no mention of a peptide dimer. Multiple limitations of the pending claims are absent in Rathjen.

Applicant requests that the *prima facia* obviousness objections to the pending claims based on Rathjen be removed consistent with the above remarks.

d.) Conclusion:

Claims have been amended or canceled consistent with suggestions made in Paper No. 12. For this and for the reasons discussed above, Applicant requests the rejections listed in Paper No. 12 be withdrawn and that the pending claims be moved on to allowance.

Respectfully submitted,
Perkins Coie LLP

Date: 4/17/03

Michael J. Wise
Registration No. 34,647

Correspondence Address:

Perkins Coie LLP
Patent – LA
P.O. Box 1208
Seattle, WA 98111-1208
Phone: (310) 788-9900
Fax: (310) 788-3399